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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,823	04/05/2001	Hisao Furitsu	0425-0832P	7747

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EXAMINER
SPEAR, JAMES M

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/806,823	FURITSU, ET AL
Examiner	**Art Unit**
JAMES M. SPEAR	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *THREE* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 10, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above, claim(s) *5-12* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-4 and 13-15* is/are rejected.

7) ☒ Claim(s) *16 and 17* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *6*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant's election with traverse of claims 1-4 and 13-17 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that applicants feel that the examiner has not established that there is an undue burden in searching for all claims as required by MPEP 803. This is not found persuasive because while group 1 and group 2 are both directed to a tablet and a method of making said tablet the methods are considered independent distinct inventions. The method requiring a difficultly soluble pharmaceutical agent and at least one of a surfactant and a water soluble polymer is considered an independent distinct inventive entity from the method

requiring a cyclic phosphodiesterase inhibitor and a saccharide.

The requirement is still deemed proper and is therefore made FINAL.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising cyclic GMP phosphodiesterase inhibitors as set forth in claims 13-15. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The structural formulas set forth in claims 13-15 are not disclosed in the specification, since the original claims are part of the disclosure, amending the disclosure by incorporating the structures would overcome this rejection. Claim 14 describes substituted groups however there is no indication as to what substituents are being described. There is no evidence presented as to how one would determine what is an effective or ineffective substituent. Claims reciting substituted in the absence of the particular effective substituent are not commensurate in scope with the disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 14, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP 2173.05(d).

In defining pharmacologically acceptable salt, the claim recites (i.e.), line 4,

considered to mean for example and therefore renders the claim indefinite.

Claims 16 and 17 are objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 97/03675. See example 3, claims 6, 8 and 11.

Claims 1-4 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 636 628 A1. See page, 5, lines 8-43, page 6, lines 38-46.

> (e)the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351 (a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Pub. No. : US 2002/0002172 A1 Bell-Huff et al.

See examples 1-3.

The reference clearly shows applicants' cyclic GMP phosphodiesterase inhibitor (sildenafil) and a saccharide in a quick disintegrating tablet and method of making said tablet. The reference further shows 50 mg tablets having disintegration times of 1 to 5 seconds. See page 2, section 0016.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Podolski US 2003/0004170 A1 shows rapidly disintegrating formulations containing sildenafil. Table 4,

Example 3. Wilson et al, US 6,403,597 shows buccal dosage forms comprised of sildenafil and other phosphodiesterase inhibitors. Example 4. Doherty, JR. et al US 2002/0004498 A1, shows sublingual sildenafil dosage forms. Example 8

Claims 1-4 and 13-15 are rejected.

Claims 16 and 17 are objected to.

Claims 5-12 are withdrawn from consideration.

Any inquiry concerning this communication or earlier communications from

the examiner should be directed to James M. Spear whose telephone number is 703 308 2457. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308 2927. The fax phone number for the organization where this application or proceeding is assigned is 703 308 4556 or 703 305 3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.

James M. Spear

January 12, 2003

James M. Spear

JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615